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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/396,196	09/15/1999	MICHAEL MITTMAN	31011	7103

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PARSONS BEHLE & LATIMER  
201 S. MAIN STREET  
SUITE 1800  
SALT LAKE CITY, UT 84111-2218

EXAMINER

ZHOU, SHU BO

ARTICLE PAPER NUMBER

1631

DATE MAILED 04/08/2003

75

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/396,196

Applicant(s)

MITTMAN ET AL.

Examiner

Shubo "Joe" Zhou

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on 7/15/02, 11/26/02, and 1/24/03.
- 2a) ☐ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☐ Claim(s) 77-95 is/are pending in the application.
- 4a) Of the above claim(s) 82-95 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) 77-81 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 24.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### **DETAILED ACTION**

Applicant's amendments and requests for reconsideration in Papers #720, 22 and 23, filed on 7/15/02, 11/26/02 and 1/24/03, respectively, are acknowledged and the amendments entered.

Applicants, in Paper #23, canceled all previous claims and added new claims 77-95. Claims 77-81 reads on the invention previously elected (canceled claims 1-16), without traverse, whereas claims 82-95 read on methods of using a microarray, as set forth in the previous Office action mailed 11/29/2000, which are non-elected inventions. Thus, only claims 77-81 are under consideration and claims 82-97 are withdrawn from further consideration as being directed to non-elected inventions.

Applicant's arguments in response to the previous Office Action of 1/14/02 have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from the previous Office action are hereby withdrawn. The following rejections and/or objections are either reiterated from the previous Office action(s) or newly added, and constitute the complete set presently being applied to the instant application.

This application contains claims 82-95 drawn to an invention non-elected without traverse in Paper No. 7. A complete reply to the final rejection must include cancellation of the non-elected claims or other appropriate action (37 CFR 1.144). See MPEP § 821.01.

### ***Information Disclosure Statement***

The Information Disclosure Statement filed on 1/23/03 is acknowledged. The references therein, however, are not considered because copies of the references are not provided to the Office.

*Specification*

The disclosure is objected to because of the following informalities:

In Paper #22, applicants amended the sequences on page 7 of the specification. However, the amendment is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows:

3'-ttggacgct-5'

3'-ttggtcgct-5'

5'-agcgtccaa-3'

5'-agcgaccaa-3'

These sequences are not supported by the originally filed specification and are considered new matter.

Applicant is required to cancel the new matter in the reply to this Office Action.

Applicants are reminded that when the new matter is canceled and if the original sequences are reinstalled, the specification still would not comply with the sequence rules because those originally filed sequences still would not be followed by a sequence identifier (SEQ ID NO:x) as required by the rules. And such sequences would have to be listed in the Sequence Listing.

*Claim Rejections-35 USC § 101/§ 112*

35 U.S.C. 101 reads as follows:

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Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The following is a quotation of the **first** paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

**Claims 77-81 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific asserted utility or a well established utility.**

Claims 77-81 are rejected for the same reasons as set forth for claims 1-16 in the previous Office action on pages 4-6, mailed 1/14/02.

Against the rejection of claims 1-16, which are not canceled, applicants argue in Paper #20 that the specification asserts a specific and substantial utility for the claims microarrays on page 13. Briefly, the microarrays can be used to compare samples by comparing hybridization patterns. This is not found persuasive because the utility is not deemed specific. The specification on page 13, lines 1-18 asserts that the invention can be used to compare gene expression patterns in samples and provide a long list of samples, such as samples treated with drugs, samples infected with virus, and samples with cancers. However, not in a single utility, does the specification provide a specific linkage between the samples, such as a specific drug, specific disease condition, and the microarray claimed. As a matter of fact, any array with any cDNAs thereon can be used to compare the gene expression pattern through hybridization patterns for any samples. What is critical is a specific nexus between the particular samples and the particular array.

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Further, the utility is not deemed substantial. Due to the absence of a specific connection between the samples tested and the microarray used, the pattern of gene expression obtained does not have a real world usage – it merely provides a gene expression pattern for the sample. Skilled person in the art would have to conduct further research to determine what the pattern means and what, if any, real world usage of the pattern.

Applicants further use the example of HPLC to argue that the microarray claimed has specific and substantial utility just like an HPLC. This is not found persuasive because the HPLC example set forth by applicants is not analogous to the present disclosure. An HPLC is a piece of equipment designed and built for a particular use. Such equipment is fully tested, evaluated, and calibrated to ensure accurate results. Those skilled in the art use HPLC to analyze both known and unknown compounds. When the compound is unknown, the results obtained are compared to results for known compounds, e.g. standards. Thus, a real world usage is to detect the presence or absence of a compound in a sample, such as the presence or absence of chlorine in a crude oil sample, a real world usage because the presence or absence of chlorine in a crude oil sample has a known real world meaning based upon prior research, i.e. there is a specific association between the presence of chlorine and the destruction of catalyst. The instantly claimed microarray, however, is merely used to obtain the gene expression pattern for a sample. The presence or absence of any nucleotide sequences on the microarray in a sample has no real world meaning absent some association. Further experimentation is required to determine what that meaning or association might be.

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**Claims 77-81 are rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.**

This rejection is made for the same reasons as set forth for the rejection of claims 1-16 in the previous Office action on pages 4-6, mailed 1/14/02.

Since applicant's arguments for the above rejection under 35 U.S.C. 101 are not deemed persuasive, the arguments in response to this rejection are deemed non-persuasive for the same reasons as set forth above.

#### ***Objections (Warning)***

Applicants are advised that should claim 77 be found allowable, claims 78-81 will be objected to under 37 CFR 1.75 as being substantial duplicates thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). In the instant case, since claims 78-81 only recite different uses of the same array, the arrays of claim 78-81 are the same as that of claim 77; thus, claims 78-81 are substantial duplicates of claim 77.

#### ***Conclusion***

No claim is allowed.

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Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703) 308-4242 or (703)305-3014.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to:  
Shubo "Joe" Zhou, Ph.D., whose telephone number is (703) 605-1158. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (703) 308-4028.

Any inquiry of a general nature or relating to the status of this application should be directed to Patent Analyst Tina Plunkett whose telephone number is (703)-305-3524, or to the Technical Center receptionist whose telephone number is (703) 308-0196.

S. "Joe" Zhou, Ph.D. 

Patent Examiner

  
MICHAEL P. WOODWARD  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600